

Motetis

tetrabenazine

25 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start taking Motetis.

This leaflet answers some common questions about Motetis. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Motetis against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Motetis is used for

Motetis is a medicine belonging to a group of medicines used to treat disorders of the nervous system.

Motetis is used for the treatment of diseases causing jerky, irregular, uncontrollable movements such as Huntington's chorea, senile chorea and hemiballismus.

Your doctor may have prescribed Motetis for another reason.

Ask your doctor if you have any questions about why Motetis has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take Motetis

When you must not take it

Do not take Motetis if you have an allergy to:

- any medicine containing tetrabenazine.
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing.
- shortness of breath.
- swelling of the face, tongue, lips, or other parts of the body.
- hives on the skin, rash, or itching.

Do not take Motetis if you:

- take reserpine (medicine used to control high blood pressure and treat psychotic states).
- take MAO inhibitors (medicine used to treat depression).
- have depression.
- suffer from Parkinson-like symptoms.
- suffer from pheochromocytoma (tumour of the adrenal gland).
- suffer from pro-lactin-dependent tumours, e.g. pituitary or breast cancer.
- have liver impairment.
- are having thoughts of harming or killing yourself.

Do not breastfeed if you are taking Motetis.

Do not give this medicine to a child. The safety and effectiveness in children has not been established.

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Motetis, talk to your doctor.

Before you start to take it

Tell your doctor if you start to have mental changes such as confusion or hallucinations or develop stiffness in your muscles and a temperature. You may be developing a condition called Neuroleptic Malignant Syndrome. **If you have these symptoms, please contact your doctor straight away.**

Tell your doctor if you have allergies to:

- any other medicines including tetrabenazine.
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have intolerance to some sugars. Motetis contains lactose.

Tell your doctor if you have, or have had, the following medical conditions:

- mild to severe hepatic impairment.
- a heart condition known as long QT syndrome or if you have or have had problems with your heart rhythm.
- trembling in the hands and jerky movements in the arms and legs, known as parkinsonism.
- high blood concentrations of prolactin (hyperprolactinemia).
- vulnerable to sudden fall in blood pressure when standing up or stretching.
- emotional or mental health conditions such as depression, past thoughts of suicide or suicide attempts, anger or agitation.

Tell your doctor if you start to have unpleasant sensations of inner restlessness, a compelling need to be in constant motion or disturbances in coordination of movements. Please consider

that tetrabenazine bind to melanin containing tissues which may affect your eyes.

Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.

Ask your doctor for advice before taking Motetis. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking Motetis.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Motetis.

Some medicines may interfere with Motetis. These include:

- levodopa (a medicine used to treat Parkinson's disease).
- antidepressants which belong to the group of medicines called monoamine oxidase inhibitors (MAOI). Treatment with MAOI should be stopped 14 days before the treatment with Motetis starts.
- drugs which affect the brain and nervous system referred to as hypnotics and neuroleptics such as:
 - opioids (pain killers)
 - metoclopramide
 - haloperidol
 - chlorpromazine
- medicines that may affect the metabolism (breakdown) of tetrabenazine resulting in the need for a reduced dose. Those include:
 - antidepressants such as fluoxetine, paroxetine.
 - quinidine, medicine for treating problems with heart rhythm.
- medicines that may affect the rhythm of the heart such as:

- certain antipsychotic medicines such as chlorpromazine, thioridazine.
- certain antibiotics such as gatifloxacin, moxifloxacin.
- Some medicines used to treat problems with heart rhythm conditions (e.g., quinidine, procainamide, amiodarone, sotalol)
- medicines used to treat high blood pressure such as beta-blockers.

Do not take Motetis together with reserpine (medicine used to treat high blood pressure and psychotic symptoms).

Do not drink alcohol while you are taking Motetis. This may cause you to feel abnormally drowsy.

These medicines may be affected by Motetis or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Motetis.

How to take Motetis

How much to take

Follow all directions given to you by your doctor or pharmacist carefully.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

The dose required varies from person to person. It depends on the condition being treated, your response to treatment and other medical conditions you have already.

Adults- Huntington's chorea, senile chorea and hemiballismus

The recommended starting dose is one tablet (25 mg) three times a day. The dose is usually increased gradually by your doctor to a maximum

of eight tablets a day (a total of 200 mg), depending on any side effects you may experience.

Adults- Tardive dyskinesia

The recommended starting dose is half a tablet (12.5 mg) a day, which can be increased as needed depending on your response to treatment.

Elderly > 65 years old

Your doctor will decide what the best dose for you is.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How to take it

Swallow the tablet(s) with water or another non-alcoholic drink. The tablet can be divided into equal doses.

When to take it

Take with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

Do not take a double dose to make up for the dose that you missed as this may increase the chance of unwanted side effects. Instead you should simply continue with the next dose when it is due.

If you are not sure what to do, ask your doctor or pharmacist.

While you are taking Motetis

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Motetis.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not give Motetis to anyone else, even if they have the same condition as you.

Do not stop taking Motetis, or lower the dosage, without checking with your doctor. Your doctor may want you to gradually reduce the amount you are using before stopping completely. This may help reduce the possibility of side effects.

Things to be careful of

Be careful driving or operating machinery until you know how Motetis affects you. It may cause drowsiness in some people. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel drowsy.

Be careful if you are over 65 years old. Some people may experience side effects such as slow movement, stiffness, and loss of balance, which may increase the risk of a fall.

Be careful when drinking alcohol while you are taking this medicine. Drinking alcohol while you are taking Motetis may cause you to feel abnormally drowsy.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital if you think that you or anyone else may have taken too much Motetis.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Motetis.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

Very common (may affect more than 1 in 10 people)

Drowsiness, fatigue, nausea, vomiting, restlessness, confusion, anxiety, involuntary blinking or eye spasms.

Motetis can cause depression. If you feel down or very sad you may be starting to become depressed and you should tell your doctor about this change.

Common (may affect up to 1 in 10 people)

Reduced appetite, diarrhoea, constipation, irritability, agitation, dizziness, headache, light-sensitivity.

Uncommon (may affect up to 1 in 100 people)

Hypothermia.

Very rare (may affect up to 1 in 10,000 people)

Sensitivity to light, palpitations, cough, dry mouth.

Unknown (not possible to estimate the incidence from available data)

Increased appetite, disorientation, forgetfulness, slowing of the heart rate, stomach pain, weight increase.

Tell your doctor immediately if you notice any of the following:

Very common (may affect more than 1 in 10 people)

Parkinson-like symptoms (uncontrollable movements of the hands, arms, legs and head), balancing problems.

Rare (may affect up to 1 in 1,000 people)

Difficulty swallowing.

Very rare (may affect up to 1 in 10,000 people)

If you start to have mental changes such as confusion or hallucinations, or develop stiffness in your muscles and a temperature, you may be developing a condition called Neuroleptic Malignant Syndrome. If you have these symptoms, please contact your doctor straight away.

Unknown (not possible to estimate the incidence from available data)

If you feel restless and feel that you cannot sit or stand still you may have something called akathisia. If you feel like this, please contact your doctor.

If any of the following happen, stop taking Motetis and tell your doctor immediately, or go to the Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.
- hives.
- fainting.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Motetis. You may need urgent medical attention or hospitalisation. These side effects are very rare.

These may be serious side effects of Motetis. You may need urgent medical attention. Serious side effects are uncommon.

Tell your doctor if you notice any other effects. Other adverse effects not listed above may also occur in some patients.

After taking Motetis

Storage

Keep your tablets in the dispensing pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.

Keep your tablets in a cool dry place where the temperature stays at or below 25°C.

Do not store Motetis in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

Motetis is a yellow, round, flat tablet with a score line on one side.

Ingredients

Active ingredient:

tetrabenazine

Inactive ingredients:

Iron oxide yellow, lactose monohydrate, magnesium stearate, pre-gelatinised maize starch, and purified talc.

Sponsor details

Motetis is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

Date of preparation

12 August 2020

(based on data sheet dated 25 May 2020)